UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re PTC Therapeutics, Inc. Derivative Litigation	) Civil Action No. 17-7216 (KM)(MAH)) Return Date: March 19, 2018) **ORAL ARGUMENT REQUESTED**

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS THE VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

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PRELIMINARY STATEMENT

This shareholder derivative suit was filed as a typical tag-along to a securities class action that is currently pending before this Court against PTC Therapeutics, Inc. ("PTC"), its Chief Executive Officer, and its former Chief Financial Officer (the "Class Action").[1] The allegations here are largely copied and pasted from the Class Action complaint, the vast majority of which were dismissed by this Court when ruling on the Class Action defendants' motion to dismiss.[2] Plaintiffs' derivative claims are dead on arrival, however, because Plaintiffs lack jurisdiction to bring suit in this Court, the sole basis for which is Plaintiffs' specious claim under Section 14(a) of the Securities Exchange Act of 1934. *See* Section I, *infra.*

Even if Plaintiffs could clear this jurisdictional hurdle—which they cannot—their claims must also be dismissed because Plaintiffs failed to first make a shareholder demand to PTC's Board of Directors ("Board"), and they cannot meet the high standard of pleading *with particularity* facts alleging that such a demand would have been futile under Delaware law. *See* Section II, *infra.* Instead,

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[1] *See In re PTC Therapeutics, Inc. Sec. Litig.*, No. 16-cv-01224 (D.N.J.) (KM) (MAH) (hereafter, the "Securities Class Action").

[2] Specifically, this Court dismissed the Class Action plaintiffs' securities fraud claims based upon the defendants' alleged misstatements occurring prior to October 15, 2015, leaving potential claims only for alleged misstatements through February 23, 2016. *In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801, at *9, 11 (D.N.J. Aug. 28, 2017).

Plaintiffs offer boilerplate allegations regarding the independence of PTC's directors, none of which come close to demonstrating that the majority of the current directors would be unable to adequately assess a shareholder demand due to a lack of independence or interest.

PTC's current Board consists of seven individuals, *six* of whom are independent and disinterested outside directors who are capable of considering a demand based on Plaintiffs' allegations.[3] Plaintiffs allege no facts sufficient to demonstrate that this supermajority of outside directors comes even close to lacking independence or exhibiting interest as required by Delaware law. Plaintiffs also allege no facts to support their conclusory allegations of the Defendants' lack of oversight, nor do they allege any "red flags" that were routinely ignored by this majority independent and disinterested Board. Instead, Plaintiffs essentially allege that the directors breached their fiduciary duties merely by virtue of being members of the Board and in some instances, signing certain SEC filings that

[3] At the time Plaintiffs commenced this action, PTC's Board consisted of seven individuals—Michael Schmertzler, Allan Jacobson, Stuart Peltz, David Southwell, Glenn Steele, Dawn Svoronos, and Jerome Zeldis—six of whom (with the exception of Ms. Svoronos)—are named as defendants, and six of whom (with the exception of Dr. Peltz) are outside directors. Verified Shareholder Derivative Complaint, *Kim v. Peltz et al.*, 17-cv-08062 (D.N.J.), filed Oct. 10, 2017 ("Compl.") ¶ 193. Pursuant to Paragraph 5 of the parties' Stipulation and Order to Consolidate Derivative Actions and Appoint Co-Lead Counsel, entered by the Court on January 3, 2018 (ECF No. 12), the operative complaint in this consolidated action was filed in *Kim v. Peltz et al.*, 17-cv-08062 (D.N.J.) on October 10, 2017.

Plaintiffs allege were false and misleading, or selling shares of PTC stock, and that therefore demand would be futile because the directors face a substantial likelihood of liability. Delaware law, however, provides that in order to demonstrate a substantial likelihood of liability, the director's conduct must be "egregious on its face"—a standard Plaintiffs fail to meet with their boilerplate allegations. *See Aronson v. Lewis*, 473 A.2d 805, 815 (Del. 1984), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000). Plaintiffs' claims must be dismissed due to their failure to make a demand of the Board or adequately plead that such a demand is futile.

Finally, Plaintiffs' state law claims must be dismissed under Federal Rule of Civil Procedure 12(b)(6). *See* Section III. For each of these three independently sufficient reasons—lack of jurisdiction, failure to plead demand futility, and failure to state a claim upon which relief may be granted, Plaintiffs' claims must be dismissed.

FACTUAL BACKGROUND

PTC is a biopharmaceutical company that develops orally administered therapies to treat rare diseases arising from genetic mutations. Compl. ¶ 2. In 2003, PTC began development of the drug ataluren (brand name Translarna™), which treats a genetic mutation called a nonsense mutation. *Id.* ¶ 97. A nonsense mutation ("nm") impedes formation of a full-length, functional protein in DNA,

and the resulting truncated, unstable protein can cause serious diseases. *Id*. ¶ 97; Ex. 3, 2014 10-K at 5-6.[4] One such disease is the rare and devastating Duchenne Muscular Dystrophy (DMD), which afflicts young boys with progressive and catastrophic muscle wasting and weakness. Compl. ¶ 99. Absent treatment, these boys typically lose the ability to walk by their early teens, require ventilation by their late teens, and die due to heart and lung failure by their mid-twenties. *Id.*; Ex. 3, 2014 10-K at 6.

Translarna is commercially available for treatment of DMD patients in over 25 countries across Europe and in other countries where European approval is recognized. Ex. 3, 2014 10-K at 3. The European Medicines Agency ("EMA"), which regulates pharmaceutical products across Europe, approved Translarna for commercial sale in August 2014 after PTC's Phase 2b clinical trial. *Id*. Despite Translarna's approval and successful use for treatment of DMD patients outside of the U.S., the U.S. Food and Drug Administration ("FDA") has not yet approved Translarna for commercial sale in the U.S. *Id.*

This derivative action arises—like the Class Action that came before it—from FDA's February 22, 2016 decision to issue a Refuse to File Letter ("RTF"), which means that FDA would not accept for filing PTC's New Drug Application

[4] References to "Ex." are exhibits to the Declaration of Adam Slutsky in Support of Defendants' Motion to Dismiss the Verified Shareholder Derivative Complaint filed herewith.

("NDA") for Translarna, and therefore would not engage in a substantive review of the evidence in the NDA, including data from PTC's human clinical trials.[5] Compl. ¶¶ 6-7, 165-70. This RTF letter was received after PTC submitted its NDA in December 2015, following two of the largest placebo-controlled clinical trials ever conducted in DMD, including the most recent trial, referred to as the Ataluren Confirmatory Trial in DMD ("ACT DMD"). Compl. ¶¶ 133, 161.

I. PTC'S MAJORITY INDEPENDENT BOARD OF DIRECTORS

At the time Plaintiffs filed their individual complaints on September 19, 2017 and October 10, 2017, PTC's Board consisted of seven directors, six of whom are outside independent directors:

- The Board Chairman, defendant Michael Schmertzler, has served on PTC's Board since 2001 and as its Chairman since 2004. During his tenure on PTC's Board, Mr. Schmertzler has served as a director, officer, or member of senior management of numerous financial institutions and early-stage biotechnology and technology companies. Compl. ¶¶ 35, 37.

- Defendant Allan Jacobson has served on the Board since its inception in 1998 and is a co-founder of the Company. Dr. Jacobson has been the Chairman of the Department of Microbiology and Physiological Systems at the University of Massachusetts Medical School since 1994. *Id.* at ¶¶ 42, 44.

- Defendant David Southwell has served as a member of PTC's Board since

[5] Following the submission of the NDA, the FDA has up to 60 days to conduct a preliminary review to determine whether it will file the application for further substantive review by its regulators. Compl. ¶¶ 107-08; Ex. 3, 2014 10-K at 35. Following preliminary review, the FDA has discretion to refuse to file the NDA if it determines that the NDA is incomplete, as PTC described in its filings with the SEC. Compl. ¶ 108; Ex. 3, 2014 10-K at 35.

2005. During his tenure on PTC's Board, he was the President and Chief Executive Officer of Inotek Pharmaceuticals (until its acquisition by Rocket Pharmaceuticals in January 2018) and also served in officer positions at Human Genome Sciences, a biopharmaceutical company, and at Sepracor, Inc, a pharmaceutical company. *Id.* at ¶¶ 59, 61.

- Defendant Glenn Steele, Jr. has served as a member of PTC's Board since 2015. He also serves as the Chairman of xG Health Solutions, and previously held the title of President and Chief Executive Officer of Geisinger Health System, an integrated health services organization. Dr. Steele has extensive experience serving on various boards and national committees in the healthcare industry. *Id.* at ¶¶ 66, 68.

- Defendant Jerome Zeldis has served as a member of PTC's Board since 2012. He is currently Chief Medical Officer and President of Clinical Development at Sorrento Therapeutics, Inc., a clinical-stage biopharmaceutical company. Until June 2016, he held various executive and senior management roles at Celgene Corporation, a public biopharmaceutical company, and has served as an assistant professor at several prominent medical schools. *Id.* at ¶¶ 63, 65.

- Non-defendant Dawn Svoronos has served as a member of PTC's Board since June 2016. She has over thirty years of experience in the pharmaceutical industry, including at Merck & Co., Inc. Ms. Svoronos currently serves on the boards of three other life sciences companies.[6]

Each of the current outside director Defendants satisfies the definition of independence pursuant to NASDAQ Rule 5605(a)(2).[7] The remaining outside

[6] *See* https://www.ptcbio.com/en/about-ptc/leadership/board-directors/.

[7] NASDAQ Rule 5605(a)(2) defines "Independent Director" as "a person other than an Executive Officer or employee of the Company or any other individual having a relationship which, in the opinion of the Company's board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director." PTC's 2017 Proxy Statement, filed publicly with the SEC, states that "Our Board has determined that all of our directors and director nominees, other than Dr. Peltz, our Chief Executive Officer, are

director Defendants, Aldrich, Koppel, Kranda, McDonough, and Renaud, are all former, independent outside directors of PTC. Compl. ¶¶ 38, 46, 49, 53, 56.

II. PTC DISCLOSED THAT ITS PHASE 2B TRIAL DID NOT ACHIEVE STATISTICAL SIGNIFICANCE AND WARNED INVESTORS THAT THE ADEQUACY OF FUTURE DATA WOULD REMAIN A "REVIEW ISSUE" FOR FDA

PTC submitted its first Translarna NDA to the FDA in early 2011 and later the European equivalent to the EMA, with each submission seeking approval of Translarna for the treatment of nmDMD. Compl. ¶ 117; Ex. 3, 2014 10-K at 6. PTC based the submissions on data from a Phase 2b clinical trial that evaluated the effect of Translarna on the ability to walk in 174 nmDMD patients between the ages of 5 and 20 (*i.e.*, the intent-to-treat, or "ITT," patient population). Compl. ¶¶ 111-12. The primary measure of this effect—or the "primary efficacy endpoint"—was a comparison between the mean change in distance that patients could walk in six minutes (the "six-minute walk distance" or "6MWD") after they received Translarna over a 48-week period and the same mean change for patients who were not treated because they received a placebo. *Id.* ¶ 112.

Following the Phase 2b trial, the FDA refused to file PTC's NDA in 2011 because, as PTC explained, the "Phase 2b clinical trial contained in the NDA did not achieve statistical significance in the pre-specified analysis." Compl. ¶ 118.

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independent as defined under applicable NASDAQ rules." Ex. 11, 2017 Proxy Statement, at 8.

After PTC received the 2011 RTF, it met with the FDA to discuss the design of a proposed Phase 3 clinical trial (later known as the ACT DMD), which would incorporate what PTC retrospectively had observed in the Phase 2b trial by, among other things, refining the trial's enrollment criteria. The ACT DMD (Phase 3) trial would focus on DMD patients who could still walk and were between 7 and 16 years of age." *Id.* ¶¶ 119-22. PTC designed the Phase 3 ACT DMD with an ITT patient population of "decline phase" boys ages 7 to 16 who could walk at least 150 meters. *Id.* ¶ 121. The primary efficacy endpoint for the trial was the same as in the Phase 2b trial: the mean change in 6MWD for patients who received Translarna over a 48-week period versus the mean change for placebo patients. *Id.* ¶ 122. In addition to the primary efficacy endpoint, the trial included secondary measures of the effect of Translarna, including timed-function tests (e.g., the time it takes to walk a flight of stairs). *Id.* ¶ 152.

Prior to completing trials, drug sponsors like PTC submit a Statistical Analysis Plan ("SAP") to FDA for review and comment. Ex. 10, 2016 10-K at 7. In addition to describing the primary efficacy endpoint, PTC's SAP also identified several subgroups of the ITT that it would analyze as part of PTC's exploration of the groups most likely to see a treatment effect, including patients who could walk at least 300 meters but less than 400 meters at the outset of the study, and the SAP also stated that PTC would conduct a "meta analysis" to include the results of ACT

DMD combined with the results from the same population who took part in the prior, Phase 2b study. *Id.*; Compl. ¶¶ 125-26. Although the FDA did not object to this patient inclusion criteria, PTC cautioned investors that "regulatory authorities typically give greater weight to results from pre-specified analyses and adjusted p-values and less weight to results from post-hoc, retrospective analyses and nominal p-values. [This] could negatively impact the evaluation by the EMA or the FDA of our anticipated applications for full marketing approval for ataluren/Translarna." Ex. 3, 2014 10-K at 57.

III. PTC EXPRESSED HONESTLY HELD BELIEFS REGARDING TRANSLARNA'S PROSPECTS AND ACCURATELY DISCLOSED THE ACT DMD RESULTS

Plaintiffs' derivative claims arise from the same ten sets of statements by PTC that the plaintiffs in the Class Action alleged were material misrepresentations,[8] with the particular statements all falling into three general

[8] Compl. ¶¶ 138-64 (alleging statements spanning ten dates between November 6, 2014 and January 13, 2016). For the Court's convenience, Ex. 1 lists why each alleged misstatement is not actionable, referring, where applicable, to the Court's prior rulings on identical misstatements alleged in the Class Action. Plaintiffs add two alleged misrepresentations beyond those alleged in the Class Action: (i) an allegation that PTC's 2015 Proxy Statement failed to disclose "material adverse facts as discussed herein" and failed to disclose the Individual Defendants' alleged failure to abide by PTC's Code of Conduct (Compl. ¶¶ 148-49); and (ii) an allegation that PTC's 2014 Form 10-K contained a materially misleading statement that PTC "incorporat[ed] our learnings from our completed trials" when designing the ACT DMD (*id.* ¶ 145). These allegations add nothing substantively to Plaintiffs' claims and are nothing more than transparent attempts to avoid dismissal, *i.e.*, to allege a basis for jurisdiction in federal court (*see* Section I, *infra*)

categories: (A) PTC's anticipated timeline, as of November 2014, for FDA review of the ACT DMD NDA, which this Court concluded in the Class Action were not sufficiently alleged to be false because the complaint "contains no factual basis to support a conclusion that these statements were false or misleading when made";[9] (B) PTC's optimism, as of early to mid-2015, regarding the then-ongoing ACT DMD, which this Court, again, concluded in the Class Action were not sufficiently alleged to be false because the complaint "fails to allege plausibly that [defendants'] statements about the risk of the ACT DMD study were false or misleading when made";[10] and (C) PTC's interpretations of the ACT DMD data and prospects for the NDA based on that data commencing on October 15, 2015.[11] Like the Class Action plaintiffs, Plaintiffs' theory is that, although PTC repeatedly disclosed the "substantial risk" that FDA and EMA would not agree with PTC's interpretation of the ACT DMD results,[12] PTC made allegedly misleadingly optimistic statements regarding the ACT DMD trial and the likelihood that the Translarna NDA would be accepted for review, while PTC knew and failed to disclose that, in the future, the FDA would take the allegedly "rare" step of sending the RTF and refusing to review the NDA. Compl. ¶¶ 14, 109. Plaintiffs further

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and to bolster their demand futility allegations (*see* Section II.B.2, *infra*).

[9] Compl. ¶¶ 137-41; *PTC Therapeutics*, 2017 WL 3705801, at *9.

[10] Compl. ¶¶ 142-43, 147, 150-51; *PTC Therapeutics*, 2017 WL 3705801, at *11.

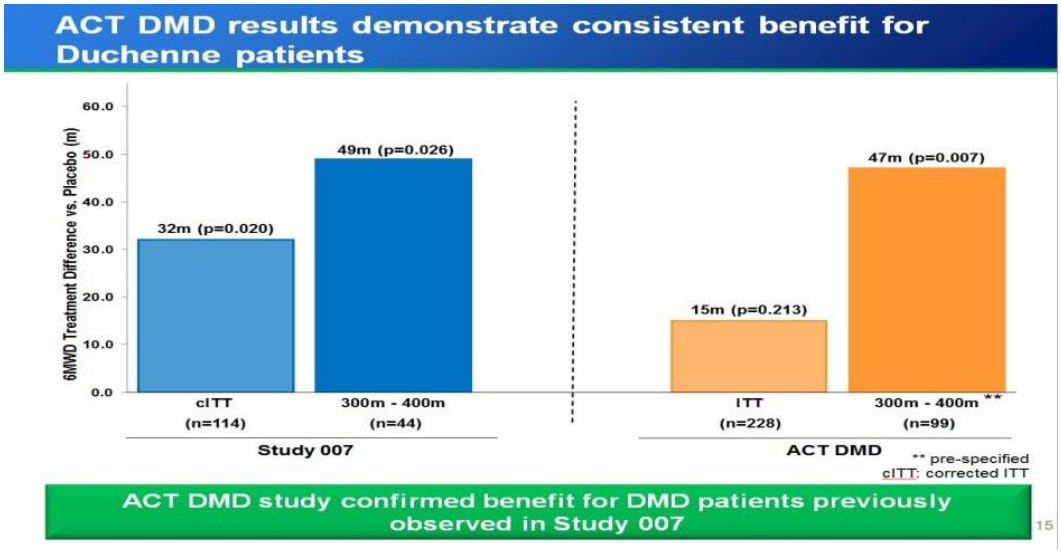
[11] Compl. ¶¶ 152-64.

[12] *See, e.g.*, Ex. 7, Q3 2015 10-Q at 40.

allege that all Defendants breached their fiduciary duties by "willfully or recklessly ma[king] and/or caus[ing] the Company to make false and/or misleading statements and/or omissions of material fact" and failing to maintain appropriate internal controls. *See id.* ¶ 223.

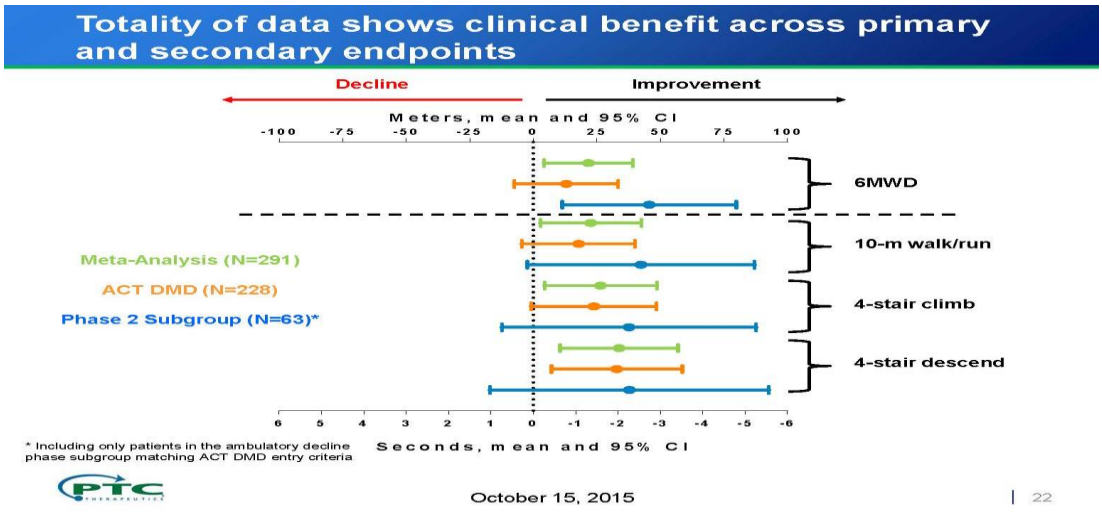
On October 15, 2015, PTC announced the results of the ACT DMD, first in a press release and then in a conference call with investors and analysts later that day. Compl. ¶¶ 152-55. During the conference call, PTC's CEO, Dr. Peltz, directed investors and analysts to PTC's publicly available presentation that summarized the trial results, which Dr. Peltz described both as lacking statistical significance (in the overall population) and demonstrating greater benefits to patients in a pre-specified 300-400 meter subgroup:

> **[I]n the overall population of ACT DMD, we saw a 15 meter difference favoring Translarna with a P value 0.0213 that was not statistically significant.** In the optimal pre-specified 300 to 400 meter baseline group, a greater benefit of 47 meters was observed with a highly significant P value of 0.007. . . .



Ex. 5, Oct. 15, 2015 Conf. Tr. at 5; Ex. 6, Oct. 15, 2015 Presentation at 15.

In the same conference, Dr. Peltz stated, "We are very pleased that the totality of the Translarna results demonstrate clinical benefit for DMD." In support of this statement regarding the "totality" of results, PTC explained both in words and in an accompanying slide the data comprising this "totality," specifically the improvement—either in meters walked for the primary endpoint or in the timed test secondary endpoints—using data from (1) the ACT DMD ITT, (2) the pre-specified meta-analysis combining the ACT DMD ITT and corresponding participants in Phase 2b, and (3) the subgroup of Phase 2b participants meeting the ACT DMD criteria:



Ex. 6, Oct. 15, 2015 Presentation at 22. There was no mystery as to what PTC meant by "totality" of results.

In PTC's next quarterly filing with the SEC on November 9, 2015, the

Company disclosed its intent to push forward with its submissions to the FDA and the EMA but was explicit about the "substantial risk" that these regulators would not agree with PTC's interpretation of the trial results:

> In October 2015, we announced the initial results of ACT DMD, including that **the primary efficacy endpoint in the ITT population did not achieve statistical significance**. We believe that the totality of clinical data from ACT DMD and our prior Phase 2b trial support the clinical benefit of Translarna for the treatment of nmDMD. We intend to submit our analyses of the ACT DMD data and meta-analysis of the combined ACT DMD and Phase 2b subgroup data to the FDA in connection with our rolling NDA for Translarna for the treatment of nmDMD as well as to the EMA in connection with our marketing authorization in [Europe], which is conditioned, among other things, on the submission of final results of ACT DMD to the EMA by the end of 2015. . . .
>
> There is **substantial risk that the FDA, the EMA and other regulators will not agree with our interpretation of the results of ACT DMD and the totality of clinical data from our trials in Translarna for the treatment of nmDMD**. . . .

Ex. 7, Q3 2015 10-Q at 40. Regulators also might not agree because PTC's "**retrospective analyses are generally considered less reliable than pre-specified analyses.**" *Id.* at 44. In January 2016, PTC announced the completion of its NDA submission to the FDA and submission of the ACT DMD results to the EMA. Compl. ¶ 133.

IV. PTC WAS SURPRISED BY THE RTF AND CONTINUES TO ADVOCATE FOR FDA APPROVAL OF TRANSLARNA

Plaintiffs allege that the "truth emerge[d]" through a series of disclosures commencing on the morning of February 23, 2016, when PTC announced that it had received a RTF from the FDA on the evening of February 22. Compl. ¶ 165;

Ex. 8, Feb. 23, 2016 8-K at Ex. 99.1. In addition to this prompt disclosure, PTC addressed the RTF in the quarterly earnings press release that it filed with the SEC six days later and on its quarterly earnings conference call:

> We are surprised by this letter, given the FDA's recent guidelines on flexibility for DMD drug development and their willingness to review NDAs of other DMD therapies that missed the primary endpoints. With regard to evidence of effectiveness, let me remind you that we have now completed two large double-blind placebo-controlled trials in over 400 nonsense mutation DMD patients.
>
> In a rare, devastating, progressive disorder we have demonstrated clinically meaningful benefit in one year studies across both primary and secondary endpoints. We believe the totality of the data is supportive of the effectiveness and demonstrates a strong safety profile.
>
> Indeed, it was on the basis of this positive benefit risk profile that the European Medicines Agency approved Translarna in August 2014.

Ex. 9, Feb. 29, 2016 Conf. Tr. at 3.

PTC filed a formal appeal of the decision to FDA, which was denied in October 2016. Compl. ¶ 171. PTC responded by filing its NDA under FDA's file-under-protest regulations, a procedural path permitted by FDA regulations that allows a company to have its NDA filed and reviewed when there is a disagreement with regulators over the acceptability of the NDA submission. *Id.* ¶ 172. Through that process, FDA granted PTC review of the NDA, including an Advisory Committee meeting that took place on September 28, 2017. *Id.* ¶ 178. After hearing hours of testimony from outside experts and representatives of PTC, as well as testimonials from DMD patients, their families, and their physicians, the Advisory Committee panel voted on its recommendation to FDA. The 11-member

Committee had three voting options: (a) the data suggest Translarna is not effective; (b) although it is possible that Translarna may be effective, the data are inconclusive, and more work is needed to establish whether Translarna is effective; or (c) the data are sufficient to conclude that Translarna is effective. Ex. 12, Excerpted Advisory Comm. Tr. The vote tally at the conclusion of the meeting was as follows: (a) – 0; (b) – 10: (c) – 1. *Id.* Not a single Committee member voted that the data suggest Translarna is not effective. *Id.*

Following the Advisory Committee's vote, FDA delivered a Complete Response Letter to PTC formally rejecting the NDA. Ex. 13, Oct. 25, 2017 8-K at Ex. 99.1. PTC has filed a formal dispute resolution request challenging this decision. *Id.* PTC continues to market and sell Translarna across Europe and in countries that recognize European approval.

PROCEDURAL BACKGROUND

Plaintiffs are a group of shareholders attempting to ride the coattails of the Class Action plaintiffs. On August 28, 2017, this Court granted in part and denied in part the Class Action defendants' motion to dismiss, holding that the Class Action plaintiffs' allegations based upon alleged misrepresentations prior to October 15, 2015—when PTC announced the ACT DMD trial results—failed to sufficiently plead falsity. The Court permitted the Class Action plaintiffs' claims based on alleged misrepresentations between October 15, 2015 and February 23,

2016 to proceed, although noting that "plaintiff's version of events is [not] factually bulletproof" and "[t]here is something to be said for the defendants' account." *PTC Therapeutics*, 2017 WL 3705801, at *19.

Within weeks of the Court's ruling in the Class Action, on September 19, 2017, shareholder Yongjoon Choi filed the first derivative complaint against PTC, Dr. Peltz, Mr. Kovacs, and certain current and former directors of PTC. *Choi v. Peltz, et al.*, Case No. 1:17-cv-07216 (D.N.J.), ECF No. 1. On October 10, 2017, Plaintiff Ned Kim, represented by the same counsel as Mr. Choi, filed a virtually identical complaint against the same Defendants, adding new allegations concerning the FDA Advisory Committee, which had convened since the filing of Plaintiff Choi's complaint. On November 29, 2017, the parties filed a stipulation to consolidate the *Choi* and *Kim* lawsuits captioned as *In re PTC Therapeutics, Inc. Derivative Litigation*, appoint co-lead counsel for Plaintiffs, and to designate the *Kim* complaint as the operative complaint in the consolidated litigation. ECF No. 11. The Court entered the order on January 3, 2018.[13] ECF No. 12. On January 10, 2018, the parties jointly requested reassignment of the consolidated action,

[13] On January 17, 2018, a third plaintiff, James Lee, represented by the same lead counsel, filed a virtually identical complaint. *Lee v. Peltz et al.*, 18-cv-00730 (D.N.J.). Although the consolidation stipulation entered in this action requires plaintiffs to move for consolidation of any newly filed derivative actions, plaintiffs have not yet served the *Lee* complaint on Defendants or moved for consolidation. Regardless, the *Lee* complaint is deficient for the same reasons as the operative complaint.

which request was granted on February 2, 2018. ECF No. 21. None of the Plaintiffs made any demand upon the Board prior to filing their complaints, alleging instead that such a demand upon PTC's Board would be futile.

ARGUMENT

I. THE COURT LACKS JURISDICTION OVER THIS DERIVATIVE ACTION

Plaintiffs' Complaint must be dismissed for the independent reason that Plaintiffs fail to state a claim under Section 14(a) of the Exchange Act, destroying the *sole basis* for federal subject matter jurisdiction over this action. Compl. ¶ 19; 28 U.S.C. § 1331. In a blatant attempt to backdoor their breach of fiduciary duty state law claims into federal court, Plaintiffs allege that Defendants violated Section 14(a) because PTC's Proxy Statement, filed on April 28, 2015, which solicited shareholder votes on director reelection and executive compensation, omitted or misrepresented the alleged misconduct in the Complaint. Compl. ¶¶ 211-18. First, this Court has already ruled in the Class Action that Defendants' statements expressing optimism regarding the outcome of the ACT DMD trial prior to October 15, 2015 are not actionable due to the Class Action plaintiffs' failure to allege that the statements were false when made. *PTC Therapeutics*, 2017 WL 3705801, at *9, 11. For the same reason, there was no alleged misconduct to conceal in the 2015 Proxy, which is Plaintiffs' only "hook" for federal jurisdiction.

Second, the Complaint fails to allege any causal link between the Proxy—which PTC filed more than six months prior to announcing the ACT DMD results—and any injury to the Company, which is fatal to Plaintiff's Section 14(a) claim. Courts have "consistently rejected" such attempts to use Section 14(a) "as an avenue for access to the federal courts in order to redress alleged mismanagement or breach of fiduciary duty," and this Court should do the same. *Maldonado v. Flynn*, 597 F.2d 789, 796 (2d Cir. 1979) (citing cases). At the motion to dismiss stage, "a court must dismiss a plaintiff's Section 14(a) claim where the plaintiff fails to show that '[the] proxy solicitations were . . . an *essential link* in the incurring of [the plaintiff's] losses.'" *Resnik v. Boskin*, 2011 WL 689617, at *3 (D.N.J. Feb. 17, 2011) (dismissing Section 14(a) claim). Here, Plaintiff's theory under Section 14(a) is that the alleged misrepresentations and omissions in the 2015 Proxy statement were material to Plaintiffs in voting to elect the Defendant directors, causing the Company to be damaged." Compl. ¶¶ 215-17. This theory of liability has been expressly rejected by the Third Circuit in *General Electric Co. v. Cathcart*, 980 F.2d 927, 933 (3d Cir. 1992), in which the Court noted that "the mere fact that omissions in proxy materials, by permitting directors to win re-election, *indirectly* lead to financial loss through mismanagement will not create a sufficient nexus with the alleged monetary loss." 980 F.2d at 933. For these reasons, Plaintiffs' Section 14(a) claim fails, and the Court should decline to

exercise supplemental jurisdiction over the remaining state law claims. *Freer v. Mayer*, 796 F. Supp. 89, 94 (S.D.N.Y. 1992) (dismissing derivative action for lack of jurisdiction where remaining breach of fiduciary duty claims are "fundamental issues of state law").[14]

II. PLAINTIFFS HAVE FAILED TO SHOW THAT DEMAND IS EXCUSED AS FUTILE

The demand requirement is an extension of the "cardinal precept" of Delaware law that boards of directors, not shareholders, manage the business and affairs of a corporation. *See Aronson*, 473 A.2d at 811. The decision of whether or not to bring a lawsuit on behalf of a corporation is therefore properly placed in the hands of the corporation's board. *Spiegel v. Buntrock*, 571 A.2d 767, 773 (Del. 1990).[15] Rule 23.1 of the Federal Rules of Civil Procedure and Delaware law thus require that any shareholder seeking to bring derivative litigation on a company's behalf must first make a demand on the company's board of directors, or plead *with particularity* the reasons why such a demand would be futile. *See Aronson*, 473 A.2d at 811-15.

Although the Court must accept well-pleaded factual allegations as true, the

[14] Plaintiffs have not alleged diversity as an alternative basis for jurisdiction. *See* Compl. ¶¶ 19-20.

[15] In a derivative action alleging state law claims, like the Delaware state law claims asserted here, a district court "appl[ies] state substantive law to determine whether the facts demonstrate [that] demand would have been futile and can be excused." *Kanter v. Barella*, 489 F.3d 170, 176 (3d Cir. 2007).

pleadings "are held to a higher standard under Rule 23.1" than the permissive notice pleading standard. *See In re Citigroup Inc. S'holder Deriv. Litig.*, 964 A.2d 106, 120 (Del. Ch. 2009). Rather, "the pleadings must comply with 'stringent requirements of factual particularity' and set forth 'particularized factual statements that are essential to the claim.'" *See id.* at 120-21 (quoting *Brehm v. Eisner*, 746 A.2d 244, 254 (Del. 2000)). Where a plaintiff fails to meet this higher standard, or offers only conclusory allegations, the complaint must be dismissed. *See id.* at 135.

Where the subject of Plaintiffs' claims is not a discrete business decision of the board, but rather the directors are sued because "they have failed to do something (such as a failure to oversee [management]), demand should not be excused . . . in the absence of allegations demonstrating why the board is incapable of considering a demand." *Rales v. Blasband*, 634 A.2d 927, 934 n.9 (Del. 1993). This extraordinarily high burden is met only if "the particularized factual allegations of a derivative stockholder complaint create a reasonable doubt that, as of the time the complaint is filed, the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand." *Kanter v. Barella*, 388 F. Supp. 2d 474, 479 (D.N.J. 2005), *aff'd*, 489 F.3d 170 (3d Cir. 2007) (quoting *Rales*, 634 A.2d at 934) (dismissing complaint because plaintiff did not adequately allege demand was futile). Consequently,

Plaintiffs here must demonstrate that a majority of the Board members—at least four directors—are either not independent or interested.

Plaintiffs have not alleged *any* particularized facts to demonstrate that a majority of PTC's directors at the time this case was filed were interested or lacked independence. Nor could they. The Complaint alleges that each of PTC's directors, aside from Dr. Peltz, is independent: Defendant Schmertlzer is not an officer or employee of PTC and has served in various roles at financial institutions and biotechnology companies during his tenure on PTC's Board; Defendant Jacobson is not an officer or employee of PTC and is Chairman of a department at the University of Massachusetts Medical School; Defendant Southwell is not an officer or employee of PTC and serves or has served other companies in an officer or director capacity throughout his tenure on PTC's Board; Defendant Zeldis is not an officer or employee of PTC and currently serves as Chief Medical Officer and President of Clinical Development at Sorrento Therapeutics, Inc.; and Defendant Steele is not an officer or employee of PTC and serves on many boards and governing bodies in the healthcare industry. *See* Factual Background, Section I. Plaintiffs make no allegations whatsoever against one member—non-party Dawn Svoronos—tacitly admitting that director Svoronos is independent, disinterested, and capable of assessing a proper shareholder demand. Compl. ¶ 193.

A. Plaintiffs Have Not Adequately Alleged that a Majority of the Board Lacks Independence.

To establish a lack of independence among the directors, a plaintiff must demonstrate that the current directors are "beholden" to an interested party, or "under an influence which sterilizes their discretion." *Aronson*, 473 A.2d at 814-15. Plaintiffs allege that six of the seven of the current Board members—*i.e.*, everyone except for non-party director Svoronos—lack independence because they received "lavish" monetary compensation from PTC for their Board service and have "large Company stock holding[s]." Compl. ¶¶ 196-01. The Complaint alleges no basis for its characterization of any Defendant's compensation as "lavish," and the Company's Proxy Statements, like the 2015 Proxy Statement cited in Plaintiffs' Complaint, set forth in detail the basis for each director's compensation. *See, e.g.*, Ex. 4, 2015 Proxy Statement, at 42-43.

In any event, it is well-established Delaware law that director compensation alone is insufficient to plead demand futility. *A.R. DeMarco Enters., Inc. v. Ocean Spray Cranberries, Inc.*, 2002 WL 31820970, at *5 (Del. Ch. Dec. 4, 2002); *see also King v. Baldino*, 648 F. Supp. 2d 609, 618 (D. Del. 2009), *aff'd sub nom. King ex rel. Cephalon Inc. v. Baldino*, 409 F. App'x 535 (3d Cir. 2010) ("The Delaware Supreme Court has held that allegations 'that directors are paid for their services as directors . . . without more, do not establish any financial interest.'"); *In re Adolor Corp. Deriv. Litig.*, 2009 WL 1325738, at *7 (E.D. Pa. May 12, 2009) ("If the

decision to pay directors, and conversely, the receipt of compensation, were enough to create a disabling interest, demand would almost always be futile. This simply is not the law."). For the same reason, mere stock ownership—even a controlling percentage, which is not alleged here—is not sufficient to plead demand futility. *See id.* (recognizing that under Delaware law, the award of stock options are a form of director compensation permitted by 8 Del. C. § 141(h) and do not excuse demand).

B. Plaintiffs Have Not Adequately Alleged That a Majority of the Board Has a Disabling Interest.

Plaintiffs' second basis for alleging futility is equally unavailing. To allege directorial interest such that demand is excused, Plaintiffs must plead particular facts showing that a director will be "*materially* affected, either to his benefit or detriment, by a decision of the board, in a manner not shared by the corporation and the stockholders." *Seminaris v. Landa*, 662 A.2d 1350, 1354 (Del. Ch. 1995). (emphasis added). Here, Plaintiffs merely allege that six of the seven current directors are interested because as "long-time director[s]" of PTC, they face liability on Plaintiffs' underlying claims against them. Compl. ¶¶ 197-201.

But the "mere threat of personal liability" is insufficient to create a reasonable doubt as to director disinterestedness, as that can be alleged in every case. *In re Johnson & Johnson Deriv. Litig.*, 865 F. Supp. 2d 545, 556 (D.N.J. 2011) (quoting *Rales*, 634 A.2d at 936). Demand may be excused only in the "rare

case" that a plaintiff articulates particularized facts showing that a director faces a "substantial likelihood of liability." *Citigroup*, 964 A.2d at 121 (dismissing claims for failure to plead demand futility); *see also In re Merck & Co., Inc. Sec., Deriv. & "Erisa" Litig.*, 2008 WL 2788400, at *5 (D.N.J. June 17, 2008) ("[A] substantial likelihood of liability can be shown in those 'rare cases' in which the board's conduct has been 'egregious.'") (quoting *Aronson*, 473 A.2d at 815). This is far from one of those "rare cases." Outside of Plaintiffs' demand futility allegations, the Complaint does not contain a single individualized allegation against any director, aside from CEO director Dr. Peltz.

Plaintiffs bring claims against all of the individual defendants for violations of Section 14(a) of the Securities Exchange Act of 1934 (prohibiting materially false statements rendering a proxy statement materially misleading) (First Claim); and breach of fiduciary duties for "willfully or recklessly ma[king] and/or caus[ing]the Company to make false and/or misleading statements and/or omissions of material fact" (Second Claim); unjust enrichment (Third Claim); abuse of control (Fourth Claim); gross mismanagement (Fifth Claim); and waste of corporate assets (Sixth Claim). Compl. ¶¶ 211-50. Taken together, Plaintiffs essentially claim that the Board's inaction in allowing the Company to make false or misleading statements or omissions constitutes a breach of fiduciary duty for failure to oversee management. Such allegations of nonfeasance are known as

"*Caremark*" claims. *In re Caremark Int'l Corp. Deriv. Litig.*, 698 A.2d 959 (Del. Ch. 1996); *see also Kanter*, 388 F. Supp. 2d at 480.[16]

Caremark claims have been recognized by courts in this district and elsewhere as "possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment." *Johnson & Johnson*, 865 F. Supp. 2d at 557 (quoting *Caremark*, 698 A.2d at 967). To meet this burden, a plaintiff must allege particularized facts to show either that the directors (1) *knew* that violations of law were occurring and took no steps to remedy or prevent them; or (2) were unaware of the violations of law because of a "*sustained or systematic* failure of the board to exercise oversight." *See Caremark*, 698 A.2d at 971 (emphasis added). Rather than pleading particularized facts, however, Plaintiffs merely assert conclusory allegations that defendants breached their fiduciary duties by "fail[ing] to correct and/or caus[ing] the Company to fail to correct the false and/or misleading statements and/or omissions of material fact" regarding the likelihood of acceptance of the NDA for full review by the FDA. Compl. ¶¶ 223-24. These boilerplate allegations are insufficient to meet the high bar the courts have set for *Caremark* claims.

[16] PTC's corporate charter also exculpates the directors from liability for alleged violations of the duty of care, such as these. *See* Ex. 2, Amended and Restated Certificate of Incorporation of PTC Therapeutics, Inc., at 28; Section III.A.1, *infra*; *Lenois v. Lawal*, 2017 WL 5289611, at *19 (Del. Ch. Nov. 7, 2017) (concluding demand was not futile because plaintiff failed to plead non-exculpated claims and dismissing derivative claims).

1. Status is Insufficient to Allege the Outside Directors Are Interested.

As the primary basis for demand futility, Plaintiffs allege the five independent, outside director Defendants' service on the Board renders them incapable of considering a shareholder demand. Compl. ¶¶ 197-201. This conclusory allegation is not sufficient to establish demand futility. *See Adolor*, 2009 WL 1325738, at *7 (the "mere fact that a board was responsible for oversight at the time the alleged wrong-doing occurred is insufficient to establish demand futility"). Plaintiffs' conclusory allegations that the outside director Defendants "conducted little, if any, oversight," "consciously disregarded his duties to monitor" and "consciously disregarded his duties to protect corporate assets" (Compl. ¶¶ 197-201), without more, do not show director interest. Plaintiffs must plead "detailed allegations concerning what the directors could have known when they approved the statements alleged to be misrepresentations." *Ji v. Van Heyningen*, 2006 WL 2521440, at *9 (D.R.I. Aug. 29, 2006) (to impute to outside directors knowledge of statements' falsity requires additional allegations connecting outside directors to day-to-day workings of corporation). No such facts are alleged here. And the allegation that certain outside directors had professional backgrounds in the life sciences, healthcare, pharmaceutical and/or biotechnology industries do not show these directors actually *knew* or *did* anything here that makes them interested. No Delaware court has held that directors with

professional experience in a general field are held to a higher standard of care in the duty of oversight context absent specific facts showing their awareness of key facts. *See Citigroup*, 964 A.2d at 128 n.63 (rejecting allegation that audit committee members with financial expertise were held to a higher standard of care in the oversight context).

Delaware courts have suggested various ways a plaintiff may meet the burden of pleading particularized facts to demonstrate the futility of demand where directors acted in bad faith, such as where a plaintiff alleges directors had personal knowledge of certain "red flags," such as "detailed, third-party reports suggesting potential accounting improprieties," where the company lacked an audit committee or that the committee met only sporadically or devoted "patently inadequate time to its work," or where the directors had direct and personal involvement in the preparation of the allegedly misleading financial statements. *See In re China Auto. Sys. Inc. Deriv. Litig.*, 2013 WL 4672059, at *8 (Del. Ch. Aug. 30, 2013). There are zero such allegations here.[17]

Courts routinely dismiss complaints for failure to plead demand futility in the absence of particularized allegations that differentiate the board at issue from the board of any other company with oversight responsibilities or to show that the

[17] Courts have also noted that directors who are not named defendants in an accompanying class action face a lesser risk of liability. *See, e.g., Ji*, 2006 WL 2521440, at *10. None of the outside director Defendants is named in the Class Action, nor is the non-defendant outside director Ms. Svoronos.

board conscientiously failed to monitor the company's operations. *See, e.g.*, *Adolor*, 2009 WL 1325738, at *7 (dismissing complaint for failure to allege a sustained or systemic failure of the board to exercise oversight); *see also King*, 648 F. Supp. 2d at 625-26 (failure to plead particular facts demonstrating directors ignored alleged "red flags," including corporate integrity agreement arising out of investigations of marketing practices, rendered demand futile); *In re ITT Corp. Deriv. Litig.*, 588 F. Supp. 2d 502, 512 (S.D.N.Y. 2008) (no demand futility where the plaintiffs alleged that the defendants disregarded red flags of company misconduct, including a government investigation and subsequent consent agreement because the complaint failed "to make the critical connection between these events and the individual Directors."). Plaintiff has not alleged that "rare case" of director conduct "so egregious on its face" that any director faces a substantial likelihood of liability that makes him interested, rendering demand on the Board futile. *Citigroup*, 964 A.2d. at 121.

2. Directors' Signatures on SEC Filings Do Not Subject Them to a Substantial Likelihood of Liability.

With regard to four out of five of the outside director Defendants—all but Defendant Steele—Plaintiffs assert that they face a substantial likelihood of liability for the additional reason that they signed the 2014 10-K filed on March 2, 2015, which contains one of the alleged misrepresentations. Compl. ¶¶ 197 (Schmertzler), 198 (Jacobson), 199 (Southwell), 200 (Zeldis). This Court has

already ruled, however, that the Class Action plaintiffs failed to allege any misrepresentations by PTC prior to October 15, 2015—misrepresentations that are virtually identical to those Plaintiffs identify in the 2014 10-K. The 2014 10-K therefore should not be an alleged source of liability to any of the Defendants in this action. *Brewer v. Breen*, 2018 WL 565267, at *7-8 (S.D.N.Y. Jan. 23, 2018) (dismissing derivative claims based on misrepresentations held to be not actionable in related securities class action).

In any event, Plaintiffs fail to provide any particularized facts to demonstrate that any of these directors were sufficiently connected to the "day-to-day workings of the corporation so that a reasonable inference could be made that they knew the true state of affairs." *See Ji*, 2006 WL 2521440, at *9; *see also Guttman v. Huang*, 823 A.2d 492, 503 (Del. Ch. 2003) (holding that allegations were "wholly conclusory" where plaintiff failed to detail "the precise roles that these directors played at the company, the information that would have come to their attention in those roles, and any indication as to why they would have perceived the accounting irregularities"). Instead, "Delaware courts routinely reject the conclusory allegation that because [allegedly] illegal behavior occurred, internal controls must have been deficient, and the board must have known so." *Desimone v. Barrows*, 924 A.2d 908, 940 (Del. Ch. 2007). Plaintiffs here offer nothing more specific, and therefore fail to adequately demonstrate that directors Schmertzler, Jacobson,

Southwell, and Zeldis face a substantial likelihood of personal liability due to their signatures on PTC's 2014 10-K.[18]

Plaintiffs' allegations do not raise a reasonable doubt as to whether any of the six outside directors are independent or disinterested. Consequently, they have failed to demonstrate that demand to this Board would be futile, and their claims should be dismissed because they failed to meet the crucial procedural requirement of making such a demand.

3. Plaintiff Fails To Allege Particularized Facts To Show That Any Defendant, Much Less Four Directors, Face a Substantial Likelihood Of Liability For Insider Trading.

Plaintiff's conclusory allegations are not sufficient to allege that demand is futile as to outside directors Jacobson and Southwell because they face a substantial likelihood of liability for insider trading-based fiduciary duty violations. For insider trading allegations to excuse demand, "it must be shown that each sale by each individual defendant was entered into and completed on the basis of, and because of, adverse material non-public information." *Rattner v. Bidzos*, 2003 WL 22284323, at *11 (Del. Ch. Sept. 30, 2003). Plaintiffs have not even attempted to allege any such facts here, nor could they when each of the alleged trades were made pursuant to the Defendants' 10b5-1 trading plans. *See*

[18] The 2014 10-K was not even alleged to contain any material misrepresentation in the Class Action. Its inclusion here is transparently designed as a hook to bolster Plaintiffs' weak demand futility allegations with respect to four of the outside director Defendants.

Section III.A.3, *infra.* The Complaint does not allege that defendants Schmertzler, Koppel, McDonough, Renaud, Zeldis, or Steele traded PTC stock during the relevant period. Compl. ¶¶ 197, 200-01. An absence of stock sales by some directors weakens the inference that the remaining directors traded on inside information. *Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 54 (2d Cir. 1995).

III. THE COMPLAINT FAILS TO STATE A CLAIM

Plaintiffs' allegations also cannot survive a motion to dismiss for the independent reason that the Complaint fails to state any substantive claim. To survive dismissal under Rule 12(b)(6), a plaintiff's factual allegations "must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). It must "do more than allege the plaintiff's entitlement to relief," rather it "has to 'show' such an entitlement with its facts." *Johnson & Johnson*, 865 F. Supp. 2d at 554 (quoting *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir.2009)). Where the plaintiff's claims sound in fraud, such as Plaintiffs' claims based on substantiality similar misstatements that are alleged in the Class Action, Plaintiffs must meet Rule 9(b)'s heightened pleading standard. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1417 (3d Cir. 1997).

A. Plaintiffs Fail to State a Claim for Breach of Fiduciary Duties.

Plaintiffs allege that all of the Individual Defendants breached their fiduciary

duties by "willfully or recklessly ma[king] and/or caus[ing] the Company to make false and/or misleading statements and/or omissions of material fact" regarding the "substantial risk" that the NDA submission would be rejected by the FDA as facially insufficient, however, to allege sufficient facts to demonstrate that the outside directors were aware of these alleged violations of their duty of care,[19] or to sufficiently assert that the alleged misrepresentations—reduced to the October 15, 2015 to February 23, 2016 period by this Court's prior ruling in the Class Action[20]—are even false or misleading.

1. Plaintiffs Fail to Plead a Claim of Breach of Fiduciary Duties Against the Outside Director Defendants.

Plaintiffs allege that each of the Outside Director Defendants breached their fiduciary duties by making or causing the Company to make false and/or misleading disclosures and failing to maintain internal controls; however, these claims must fail for the same reasons set forth above in Section II.B. As

[19] Notwithstanding Plaintiffs' attempt to frame their Second Claim as a claim for breach of the "fiduciary duties of candor, good faith, and loyalty," Compl. ¶ 220, it is well-established that an allegation that directors breached their fiduciary duty by failing to oversee management sets forth a claim for breach of the duty of care. *See Caremark*, 698 A.2d at 971.

[20] As a result of the Court's prior ruling in the Class Action finding PTC's alleged misrepresentations prior to October 15, 2015 nonactionable, at a minimum, the claims against defendants Aldrich and Kranda, who left PTC's Board in June 2015, should be dismissed. *See Brewer*, 2018 WL 565267, at *7-8 (dismissing derivative claims based on misrepresentations identical to those determined to be nonactionable in related securities class action)

previously discussed, to adequately plead such *Caremark* claims, Plaintiffs must allege particularized facts to show either that the directors (1) *knew* that violations of law were occurring and took no steps to remedy or prevent them; or (2) were unaware of the violations of law because of a "sustained or systematic failure of the board to exercise oversight." *See Caremark*, 698 A.2d at 971. Where a corporation's charter exculpates directors from liability for breach of their duty of care, as PTC's does,[21] a plaintiff must plead facts showing that directors "had actual knowledge of the alleged wrongdoings at the time they were committed." *City of Roseville Employees' Ret. Sys. v. Crain*, 2011 WL 5042061, at *7 (D.N.J. Oct. 24, 2011). Failing to do so results in dismissal, because no money damages are available from these directors under the exculpation provision. *See In re Alloy, Inc. S'holder Litig.*, 2011 WL 4863716, at * 14 (Del. Ch. Oct. 13, 2011) (dismissing complaint where an "exculpatory provision . . . precludes monetary liability against the Alloy Defendants").

Plaintiffs' allegations that the Outside Director Defendants allowed the Company to disseminate inaccurate information and ignored problems with PTC's internal controls are based solely on their status as Board members and certain of them having signed the 2014 10-K Compl. ¶¶ 192-201. There are no allegations that any Outside Director Defendant knew they were not discharging their

[21] *See* Ex. 2, Amended and Restated Certificate of Incorporation of PTC Therapeutics, Inc., at 28; 8 Del. C. § 102(b)(7).

fiduciary obligations or failed to act in good faith. In fact, Plaintiff has failed to adequately allege that any of PTC's SEC filings even contained inaccurate information, *see* Ex. 1, let alone that any of the Outside Director Defendants knew of any inaccuracies in PTC's SEC filings. And as explained above in Sections II.B.1 and II.B.2, neither service on the Board nor signing SEC filings, without any additional particularized facts as to each director's role, is sufficient to demonstrate that the directors knowingly disregarded their fiduciary duties. *See China Auto. Sys.*, 2013 WL 4672059, at *8 (holding that neither "being a director on the committee where the alleged wrongdoing is within its delegated authority" nor "[a] mere statement that the defendants caused the filing of the allegedly misleading financial statements with the SEC" is a particularized allegation of fact sufficient to meet the *Caremark* standard). As Plaintiffs have failed to set forth any particularized facts to support their conclusory allegations, Plaintiffs' claims against the Outside Director Defendants must be dismissed.

2. Plaintiffs Fail to Plead a Claim of Breach of Fiduciary Duties Against the Officer Defendants.

The Second Claim against Officer Defendants Peltz and Kovacs must be dismissed because Plaintiffs fail to allege that the allegedly false and misleading disclosures were materially false. To adequately set forth a claim for breach of fiduciary duty for the dissemination of false information, Plaintiffs must sufficiently allege that the challenged statements are materially false and that the

individual defendant knowingly disseminated the information. *See Malone v. Brincat*, 722 A.2d 5, 9, 14 (Del. 1998). This requirement is "similar to, but even more stringent than, the level of scienter required for common law fraud." *See Metro Commc'ns Corp. BVI v. Advanced Mobilecomm Techs. Inc.*, 854 A.2d 121, 158 (Del. Ch. 2004). Here, this Court has already concluded that Defendants' statements prior to October 15, 2015 are not actionable because they were not adequately alleged to be false.[22] *See* Ex. 1. To the extent that this Court found that the Class Action plaintiffs narrowly satisfied their pleading requirements with respect to Defendants' statements between October 15, 2015 and February 23, 2016 regarding the ACT DMD trial results based on Defendants' statements that the "totality" of the data "confirmed" the clinical benefit of Translarna, Defendants have attached hereto as Exhibit 6 an additional slide from PTC's October 15, 2015 teleconference. In slide 22 of Exhibit 6, PTC clearly identifies the "totality" of data on which it relied—data which did not include the 300-400 meter subgroup or the post-hoc meta-analysis of that subgroup. Therefore, Defendants respectfully request that this Court reconsider that aspect of its prior Opinion when deciding Defendants' motion to dismiss in this action. *See, e.g.*, *PTC Therapeutics*, 2017 WL 3705801, at *14 (concluding falsity of Defendants' statements regarding ACT

[22] Defendants incorporate by reference the arguments set forth in their briefing in support of their Motion to Dismiss the Class Action Complaint. *See In re PTC Therapeutics, Inc. Securities Litigation*, No. 16-cv-01224 (D.N.J.) (KM) (MAH) ECF Nos. 56, 60.

DMD trial results sufficiently alleged because "PTC did not disclose that the primary (and perhaps only) factual support for its claim that 'totality' and 'consistency' of the ACT DMD and 2b data was the post hoc meta-analysis of the 300-400 meter subgroup"). Consequently, Plaintiffs fail to plead any actionable misstatements, and thus the breach of fiduciary duty claim against the Officer Defendants must be dismissed.

3. Plaintiffs' Insider Trading Allegations Do Not Support Their Claims.

Plaintiffs allege that six of twelve Individual Defendants sold PTC stock based on material non-public information about the Company, thereby "demonstrat[ing] his motive in facilitating and participating in the fraud." Compl. ¶¶ 28 (Peltz), 34 (Kovacs), 41 (Aldrich), 45 (Jacobson), 52 (Kranda), 62 (Southwell)—but not Defendants Schmertzler, Koppel, McDonough, Renaud, Steele, and Zeldis, and not non-defendant Svoronos. But the Defendants' trades fail to support any improper motive because each sale was conducted pursuant to non-discretionary 10b5-1 trading plans.[23] A breach of fiduciary duty claim premised on insider trading arises where "1) the corporate fiduciary possessed material, nonpublic company information; and 2) the corporate fiduciary used that information improperly by making trades because she was motivated, in whole or in part, by the substance of that information." *In re Oracle Corp.*, 867 A.2d 904,

[23] There were no insider trading allegations in the Class Action.

934 (Del. Ch. 2004), *aff'd* 872 A.2d 960 (Del. 2005). That is, "insider trading claims depend importantly on proof that the selling defendants acted with scienter." *See Guttman*, 823 A.2d at 505.

Plaintiffs, however, cannot allege scienter because all of the alleged insider stock sales were executed pursuant to a 10b5-1 trading plan,[24] which "supports the reasonable inference that stock sales were pre-scheduled and[, therefore,] not suspicious." *Stiegele ex rel Viisage Tech., Inc. v. Bailey*, 2007 WL 4197496, at *13 (D. Mass. Aug. 23, 2007). Courts in this Circuit regularly find that trades made pursuant to 10b5-1 plans are of minimal value in establishing an inference of scienter. *See Lovallo v. Pacira Pharms., Inc.*, 2015 WL 7300492, at *13 (D.N.J. Nov. 18, 2015); *see also In re Audible Inc. Sec. Litig.*, 2007 WL 1062986, at *12 (D.N.J. April 3, 2007) ("[E]vidence that . . . stock sales were made via Rule 10(b)5–1 plans . . . would prevent those shares from being considered in the motive and opportunity analysis.").

Plaintiffs' insider trading allegations also fail to support their claims because

[24] The Forms 4 filed with the SEC for each trade state that the sales reported in the Forms were effected pursuant to a Rule 10b5-1 trading plan adopted by the reporting person. *See* Ex. 14 (Defendants' Form 4s corresponding to relevant stock transactions). The Court may consider the Form 4s on a motion to dismiss because they are public SEC filings and because Plaintiffs incorporated the Forms' stock sale information into the Complaint. *See Sapir v. Averback*, 2016 WL 554581, at *10 (D.N.J. Feb. 10, 2016) (on a motion to dismiss, a Court may consider "matters of which a court may take judicial notice, such as SEC filings, press releases, and earnings call transcripts").

the alleged insider sales all occurred on or before July 6, 2015, prior to PTC's conclusion of the ACT DMD trial and more than three months prior to PTC's alleged October 15, 2015 misrepresentations regarding the trial results. This Court has already ruled that the Class Action plaintiffs failed to state a claim with respect to alleged misrepresentations prior to October 15, 2015, and thus, there was no alleged artificial inflation of PTC's stock price caused by any alleged misrepresentations at the time of the Defendants' trades. *See Brewer*, 2018 WL 565267, at *7-8.

B. Plaintiffs' Remaining Claims Fail.

Plaintiffs assert additional common law counts for variants of the breach of fiduciary duty claims—unjust enrichment (Third Claim), abuse of control (Fourth Claim), gross mismanagement (Fifth Claim), and waste of corporate assets (Sixth Claim). Courts routinely reject such transparent attempts by plaintiffs to convert legally insufficient breach of fiduciary duty claims into alternative causes of action. *See, e.g.*, *City of Roseville*, 2011 WL 5042061, at *12 (dismissing claims for gross mismanagement, abuse of control, corporate waste, and unjust enrichment premised on insufficiently pleaded breach of fiduciary duty claim). Delaware does not even recognize Plaintiffs' additional claims as independent causes of action. *See Citigroup*, 964 A.2d at 114 n. 6 (Delaware law does not recognize an independent cause of action against corporate directors and officers

for reckless and gross mismanagement but rather treats such claims as claims for breach of fiduciary duty); *In re ALH Holdings, LLC*, 675 F. Supp. 2d 462, 482–83 (D. Del. 2009) (categorizing abuse of control as a breach of directors' duty of loyalty); *Hampshire Grp., Ltd. v. Kutter*, 2010 WL 2739995, at *35 (Del. Ch. Jul. 12, 2010) ("The waste test is just another way to examine whether a fiduciary breach has been committed."); *Seidman v. Clifton Savs. Bank, S.L.A.*, 14 A.3d 36, 46 (N.J. 2011) (finding that corporate waste is actionable only based on board action, not board inaction, in authorizing an exchange that is so one-sided that no sound business judgment could be presumed). Thus, for the same reasons that Plaintiffs have failed to sufficiently allege a breach of fiduciary duty, their additional claims must also be dismissed.

CONCLUSION

This action is subject to complete dismissal on three wholly independent grounds. First, Plaintiffs' claims should be dismissed for lack of jurisdiction due to the insufficiency of their sole federal claim under Section 14(a). Second, even if this Court had jurisdiction over this lawsuit, Plaintiffs failed to satisfy the requisite procedural step of making a shareholder demand on the Board of Directors, and fail to adequately allege that such demand would be futile. Nor could they, given that a supermajority of PTC's directors are independent and disinterested. Plaintiffs' claims are subject to dismissal due to their failure to satisfy the

requirements of Rule 23.1.

Even if the Court were to find that Plaintiffs adequately alleged futility, however, Plaintiffs' claims must be dismissed because Plaintiffs fail to set forth particularized facts to support their breach of fiduciary duty claims. Instead, Plaintiffs have set forth boilerplate language that was copied and pasted from the pending Securities Class Action. These conclusory allegations do not meet the exacting standard required to prove breach of the duty of care, and consequently, Plaintiffs' claims must be dismissed.

Respectfully submitted,

Defendants
By their attorneys,

/s/ Kate D. Seib

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Dated: February 12, 2018

CERTIFICATE OF SERVICE

I, Kate D. Seib, certify that a copy of the foregoing Defendants' Memorandum of Law in Support of Their Motion to Dismiss the Verified Shareholder Derivative Complaint, filed through the CM/ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) on February 12, 2018

/s/ *Kate D. Seib*
Kate D. Seib